PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group 1635

In re the Application of

Arrigo DeBenedetti *et al.*

Examiner J.E. Angell

Serial No. 09/916,017

Filed: July 26, 2001

For: "Cancer Gene Therapy Based on Translational Control of a Suicide Gene"
(Atty. File No. 00S08)

RESPONSE TO RESTRICTION AND ELECTION REQUIREMENT

Box Non-Fee Amendment
Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the February 7, 2002 Restriction Requirement, Applicants provisionally elect Group II (Claims 10-18) with traverse.

In response to the election of species requirement, applicants elect the species corresponding to the DNA sequence that when transcribed produces an untranslated region of the mRNA that

CERTIFICATE

I hereby certify that this Response to Restriction and Election Requirement is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Box Non-Fee Amendment, Commissioner for Patents, Washington, D.C. 20231 on March 7, 2002.

Bonnie J. Davis
Registration No. 41,699
March 7, 2002

comprises the 5' untranslated sequence of fibroblast growth factor-2. Claims 10, 11, 13-15, and 17-18 read on the elected species.

Traversal of Restriction Requirement

The Office entered a two-way restriction between Group I (Claims 1-9) and Group II (Claims 10-18). The Office stated that Groups I and II were distinct because the Groups were related as product and process of use, and that the product as claimed could be practiced with another materially different process (MPEP §806.05(h)). The Office stated that the product (the DNA sequence of Group II) could be used in another materially different process, giving the examples of "expressing a polypeptide in a bacterial cell for purification or to raise antibodies." The Office also asserted that the Groups would require a different field of search.

MPEP §806.05(h) states that "[a] product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product, or (B) the product as claimed can be used in a materially different process."

The product in the independent product claim Claim10 as claimed requires a DNA sequence that comprises "a constitutive promoter linked to a transcription sequence" that "produces a messenger RNA sequence," which consists both of a translatable sequence that encodes a toxin and of an untranslated sequence that "inhibits translation of the toxin sequence in the absence of eukaryotic initiation factor eIF4E." This DNA sequence cannot be expressed as a polypeptide in a bacterial cell under normal conditions; a bacterial cell does not possess the eukaryotic factor eIF4E necessary to translate the toxin mRNA. Moreover, this DNA sequence as claimed will only produce a peptide or protein that is a toxin, and will only produce such toxin in the presence of the eukaryotic initiation factor eIF4E. To produce antibodies to a toxin requires giving the animal a measured,

sublethal amount of the toxin. Using this DNA sequence as claimed would not allow sufficient control of the amount of toxin produced. Thus it is respectfully submit that this restriction is improper, and that Groups I and II should be rejoined.

Additionally, for there to be a proper restriction requirement, there must be a serious burden on the Examiner if restriction is not required. M.P.E.P. § 803 states: "For purposes of the initial requirement a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02."

As shown in the Office Action, the classification of both Group I and Group II is the same class (514) and subclass (44). The Office stated that the search required for Group I is for therapeutic compounds, while the search for Group II is for the product only. However, the therapeutic compounds in Group I are the same products as claimed in Group II. Thus it is respectfully submitted that Groups I and II should be rejoined and the restriction requirement withdrawn.

Additionally, if the restriction requirement is maintained and if the product claims of Group II are allowed, Applicants submit that the process claims of Group I (Claims 1-9) which include all the limitations of the product claims in Group II (Claims 10-18) should be rejoined pursuant to MPEP § 821.04 and the procedures set forth in the *Official Gazette Notice* dated March 26, 1996 (1884 O.G. 86). Section 821.04 states: "If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined."

Miscellaneous

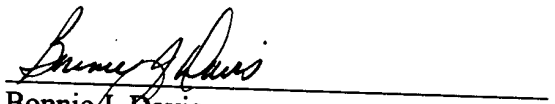
If any extension of time is required, please consider this paper a petition for the tota extension of time required.

It is believed that no fee is due in connection with this paper. In the event that a fee is due, kindly refer to the general Deposit Account Authorization previously filed with the application.

Conclusion

Applicants provisionally elect with traverse Group II (Claims 10-18). It is respectfully requested that the restriction requirement be reconsidered; Applicants submit that Groups I (Claims 1-9) and II (Claims 10-18) should be rejoined.

Respectfully submitted,



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